REMARKS

Claim Rejections – 35 USC § 102

Examiner rejects claims 1-8, 13-16 and 22, broadly interpreted, as being anticipated by Rubin.

As amended, applicants' independent claim 1 recites that "said therapeutic agent is *separate and distinct from said vasoconstrictor itself*." This amendment limits the broad interpretation referred to by examiner, and as discussed further below, clearly overcomes the prior art rejection based on Rubin.

The invention by Rubin is used solely for the treatment of male impotence, and makes no disclosures or suggestions and has no motivation beyond this limited purpose. Rubin utilizes the combination of a vasodilator and a vasoconstrictor in a carrier that includes an agent to assist absorption of the active ingredients through the skin of the penis. The function of the vasodilator and vasoconstrictor is *to specifically affect the vascular structures* of the penis which allow for engorgement and erection, and the vasodilator and vasoconstrictor *are themselves the active therapeutic agents* for this purpose. By facilitating (via vasodilator) and sustaining (via vasoconstrictor) venous engorgement of the penis, a prolonged erection is achieved, allowing for successful and pleasurable sexual intercourse. In short, Rubin merely simulates the natural phenomenon of erection and intercourse in otherwise-healthy individuals. Examiner herself appear to recognize this, having stated that "the Rubin *vasoconstrictor functions to treat impotence*."

Rubin's invention requires use of a vasodilator that works

quickly, and in synchrony with a slower acting vasoconstrictor. These two agents working synergistically *are the sole therapeutic agents* of this invention and their goal is sustained vascular engorgement of the penis.

In applicants' invention as specified by amended claim 1, the therapeutic agent is recited to be *separate and distinct from* the vasoconstrictor itself, and so it is no longer possible to interpret claim 1 broadly to suggest that the vasoconstrictor could be the therapeutic agent as in Rubin. In Rubin, the therapeutic agent is *not separate and distinct* from the vasoconstrictor itself, because *the therapeutic agent comprises the vasoconstrictor itself*. Additionally, in applicants' invention there is no vasodilator *per se*, but merely a penetration enhancer designed to facilitate subcutaneous entry of a vasoconstrictor and the *therapeutic agent separate and distinct from the vasoconstrictor*. The vasoconstrictor in applicants' invention is *not* the therapeutic agent but is used to retard vascular dispersion of the *separate and distinct therapeutic agent* so as to maintain localized therapeutic relief at the site of penetration. The therapeutic agents specifically cited in applicants' dependent claims, are for relieving pain, and for treating a viral disease. In no case are these agents specified to be a vasoconstrictor. More generally, applicants' invention uses the penetration enhancer and the vasoconstrictor, respectively, to deliver a separate and distinct therapeutic agent below the skin, and then to maintain that separate and distinct therapeutic agent in place for a prolonged period of

time to provide therapy.

In applicants' invention, there is no use of a direct vasodilator, nor is vasodilatation a therapeutic goal as it is in the case of facilitating an erection. In the pain relief embodiment, applicants' invention utilizes local anesthetic for achieving and sustaining topical site-specific analgesia. Vasodilatation and subsequent drug dispersion by vascular uptake are known effects of local anesthetics, so applicants employ a vasoconstrictor to retard these effects, and thereby maintain and prolong the local anesthetic (+NSAID) analgesia at the pain site. Applicants do not claim, nor do they intend to claim, any specific therapeutic effect of the vasoconstrictor. The sole utility of the vasoconstrictor is to enhance and sustain localization of the therapeutic effects of the *separate and distinct* therapeutic agent.

In sum, the respective purpose and effects of the vasoconstrictor in these two inventions are very different. Rubin's invention does not anticipate or suggest or motivate applicants' novel specific use of a vasoconstrictor, as claimed, to prolong and enhance the effects of topically-applied, *separate and distinct*, therapeutic agents at the site of application.

Allowable Subject Matter

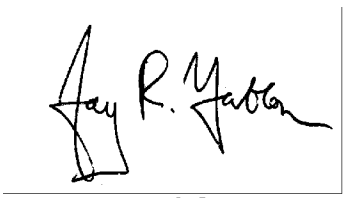
Applicants appreciate and thank examiner for the previous indication of allowability for claims 9-12, 17-21 and 23-65, and the allowance of claims 66-150.

As stated earlier, if the this reply does not result in allowance of all claims, applicants' counsel hereby respectfully requests a telephone interview with examiner Sharon E. Kennedy, following receipt of this reply, and prior to issuance of any further office action.

Conclusion

Based on the foregoing amendment and remarks, applicants respectfully requests allowance of all claims at this time, and looks forward to receiving a notice of allowance in the near future.

Respectfully submitted,



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